DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 18-826/S-026

JUN 5 1999

Abbott Laboratories
Hospital Products Division
Attention: Ms. Jill N. Sackett
200 Abbott Park Road
D-389 Bldg. AP30
Abbott Park, IL 60064-3537

Dear Ms. Sackett:

Please refer to your supplemental new drug application dated July 24, 1998, received July 31, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dopamine HCI in 5% Injection in Flexible Containers.

We acknowledge receipt of your submissions dated February 4 and April 30, 1999. Your submission of April 30, 1999 constituted a complete response to our January 13, 1999 action letter.

This supplemental new drug application provides for final printed labeling revised as follows:

Under **PRECAUTIONS: Weaning,** a period was added after "IV fluids," the word "since" was deleted, and a new sentence was started with the word "Sudden."

Under **PRECAUTIONS**, the following **Geriatric Use** subsection was added:

> Clinical studies of dopamine injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

The following sentence was added to the end of the **DOSAGE AND ADMINISTRATION: Rate of Administration** subsection:

> When discontinuing the infusion, it may be necessary to gradually decrease the dose of dopamine HCl while expanding the blood volume with IV fluids to prevent the development of marked hypotension.

The Caution statement at the end of the **HOW SUPPLIED** section was replace with "Rx only."

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted May 4, 1999). Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 3 14.80 and 314.81.

If you have any questions, please contact:

Mr. David Roeder
Regulatory Health Project Manager
(301) 594-5313

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: